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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/753,848	01/08/2004	German Trabada	10121/01301	6030
7590 Fay Kaplun & Marcin, LLP Suite 702 150 Broadway New York, NY 10038		02/01/2008	EXAMINER DAWSON, GLENN K	
			ART UNIT 3731	PAPER NUMBER
			MAIL DATE 02/01/2008	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

Application No.

10/753,848

Applicant(s)

TRABADA ET AL.

Examiner

Glenn K. Dawson

Art Unit

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 07 September 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-13,22,24 and 25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5,7-13,22,24,25 is/are rejected.
- 7) ☒ Claim(s) 6 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

***Response to Amendment***

Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn. The pre-appeal conference established that the rejection of record was not sufficiently clear in setting forth the specific combination of elements of the cited references. The following action reiterates the previous rejections and adds clarifying language to clearly state on the record the specific modifications being made, and the examiner has included a drawing figure showing the ending structure of the combination.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-5 and 7-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Richter-EP 0 976 417 in view of Cohen-5167239.

Richter discloses a guide track (inner catheter) and a modular device (outer catheter) [see paragraph 0001, 0009-0011, 0019, 0020]. It is disclosed that either the inner catheter can have the motor fixed to it and the outer surface of the motor interacts with the inner surface of the outer catheter and causes relative movement between the two catheters, depending on which of

the two is secured. Or vice-versa... the motor could be fixed inside the outer catheter and the inner bore of the motor has the friction surface and grips the inner catheter and relative movement is again achieved depending on which of the two is secured. In the option where the outer catheter (modular device) has the motor fixed to its inner surface, the modular device then includes the claimed drive mechanism (motor) for engaging the guide track (inner catheter) to move the modular device (outer catheter) relative to the guide track (inner catheter). The examiner contends that prior to the inner catheter (guide track) entering the bore of the motor, that the modular device (outer catheter) is not coupled to the guide track (inner catheter). Once the inner catheter is threaded into the motor's internal longitudinal bore and the friction surface of the motor engages the outer surface of the guide track (inner catheter), the two (modular device and the guide track) are indeed coupled at that point. Because the user could determine when the guide track became coupled to the modular device, the examiner contends that the modular device is indeed "selectively coupleable to the guide track. Securing either catheter could be done externally, or could be done via balloons near their distal ends and inflated to engage the vessel lumen wall.

Richter goes on to disclose how the user can select which catheter or member is secured thus causing the other one to relatively move.

Richter, however, fails to disclose the anchoring module selectively coupleable to the guide track for anchoring the guide track at the desired location in the vessel lumen. Cohen discloses a guidewire with a distal anchoring balloon. The guidewire uses the balloon to anchor the guidewire in position in the vasculature during catheter procedures. It would have been obvious to have placed the guidewire of Cohen through the inner lumen of the guide track (inner catheter) of Richter, as this would provide a means by which the catheters could be initially guided into position and then the guidewire could be anchored, thus facilitating the proper positioning of the catheters and the performance of catheter procedures. As Richter discloses that motors fixed to guidewires could be used to pull a guidewire relative to a catheter which it is placed in, or vice-versa pull a catheter over a guidewire depending on whether the motor is fixed to the outer surface of the guidewire or the inner surface of the catheter, the examiner contends that merely duplicating the use of a motor such as that taught by Richter to move the guidewire relative to the guide track (inner catheter) would have been another obvious modification. This has been shown to be an effective manner in which to position catheters and guidewires

in a vascular lumen, as opposed to simply pushing such devices, because this reduces the likelihood that the device will get caught in a curve of a lumen or cause trauma to the lumen.

Therefore, the proposed combination is one in which two motors are utilized to cause relative movement between the three (3) components. As discussed above, the examiner contends that prior to the guidewire (anchoring module) entering the bore of the motor, if placed inside the guide track (inner catheter), or vice versa, prior to the guidewire with motor being placed inside the guide track (inner catheter), that the guidewire (anchoring module) is not coupled to the guide track (inner catheter). Once the guidewire is threaded into the motor's internal longitudinal bore, or the guidewire and motor is threaded into the guide track, and the friction surface of the motor engages respective surface on the guidewire (anchoring module) or the guide track (inner catheter), the two (anchoring module and the guide track) are indeed coupled at that point. Because the user could determine when the guidewire (anchoring module) became coupled to the guide track (inner catheter), the examiner contends that the anchoring module (guidewire) is indeed "selectively coupleable to the guide track".

So to summarize, the guide track is the inner catheter of Richter; the modular device is the outer catheter of Richter, and the anchoring module is the balloon anchoring guidewire of Cohen placed inside the inner catheter of Richter. The three elements are indeed selectively coupleable relative to each other and capable of causing the claimed relative movement of the various elements.

With respect to claim 2, the guide track is either a catheter or a guidewire.

With respect to claim 3, the elements could be re-identified in a different manner such as the guide track could be the guidewire, the modular device could be the inner catheter and the anchoring module could be the outer catheter. In this context, the outer catheter is selectively coupleable to the guide track or guidewire through the selective coupling of the outer catheter to the inner catheter and the inner catheter to the guidewire. As shown in fig. 3 element 24 of Cohen is the claimed helical contact surface on the outer surface of the guide track (guidewire) and the motor could engage and move over this helical surface.

With respect to claim 4, a motor would be present in the inner catheter and/or the outer catheter.



With respect to claim 5, Richter discloses that the motor is energized by wires connected to the motor. Since it can be activated and deactivated, it stands to reason that there is an external switch or control knob and power source. Providing an external power source for the motor would have simplified the motor by not requiring it to contain its own power source.

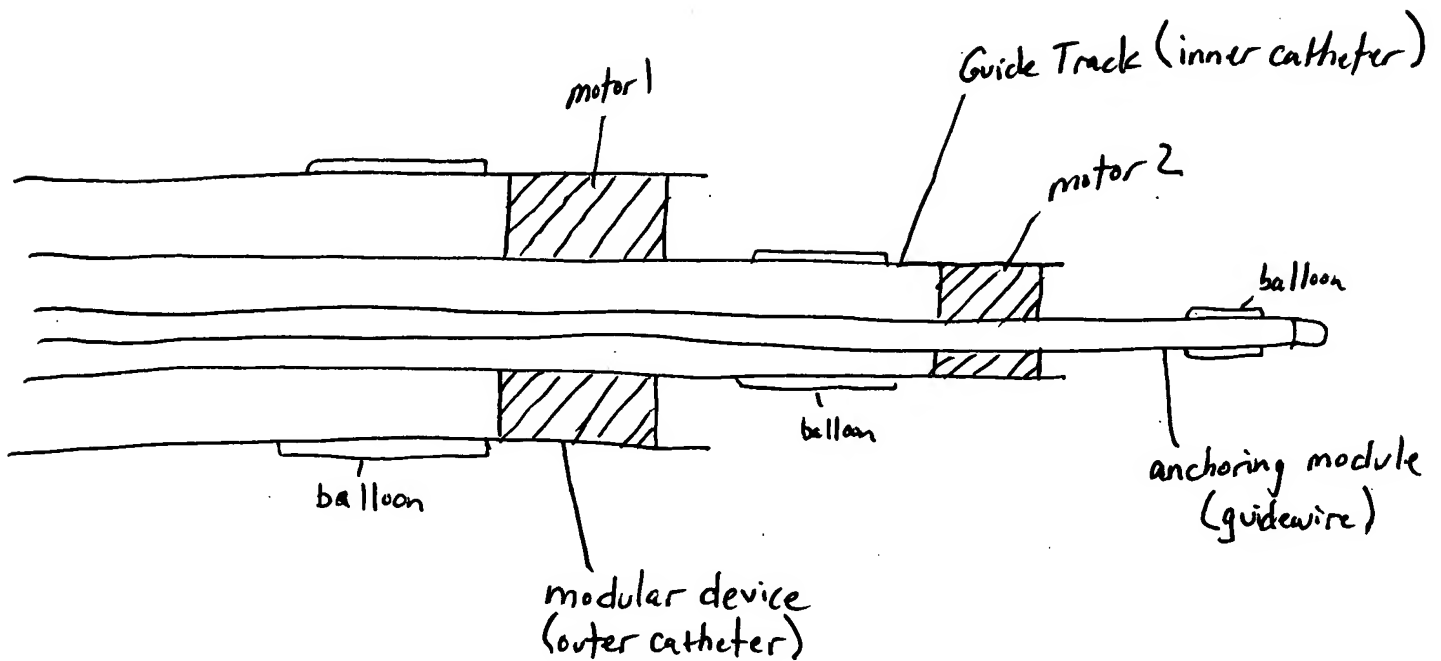
With respect to claim 7, the outer catheter has a lumen for receiving both the guide track and anchoring module therein.

With respect to claim 9, the anchoring module (balloon guidewire of Cohen) is moveable along the guide track (inner catheter) and is capable of anchoring the guide track when the guidewire was engaged with the guide track and the balloon on the guidewire were inflated to engage the vessel wall.

With respect to claims 10 and 11, the extendible member is the balloon 14 and the inflation lumen is 26.

With respect to claims 12 and 13, providing a balloon on the modular device (outer catheter) would have been obvious in order to perform angioplasty, to expand a stent, to form a chamber between it and the guidewire balloon for performing a procedure while preventing migration of emboli... etc..

As an inflation lumen for this balloon would be necessary to inflate the balloon, providing such would also be obvious.



Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Richter-EP 0 976 417 in view of Cohen-5167239 as applied to claim 1 above, and further in view of Kindlein-7229401.

With respect to claim 8, the applicant has never questioned or argued against the obviousness of the drive mechanism including gears moveable

between an engaging position and a retracted position. While not specifically disclosed by Richter, the examiner contends it would have been obvious to have provided the motor of Richter with such gears as they would be an obvious known mechanism for providing the disclosed frictional surface for causing the relative movement. See for example Kindlein-7229401 fig. 6. This retractable mechanism allows for easier feeding of the inner element into the friction zone of the drive mechanism.

Claims 22-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Richter-EP 0 976 417 in view of Cohen-5167239 and further in view of McAllister-2002/0065523

Richter as modified by Cohen discloses the device and method as claimed with the exception of the resection being performed. McAlister discloses the guiding of a catheter to a location to perform a resection procedure. It would have been obvious to have used a resection catheter as the modular catheter device disclosed by Richter which crawls along a catheter, as it would be a convenient manner in which to guide the catheter into position without causing it to buckle, which can occur during pushing.

***Allowable Subject Matter***

Claim 6 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Response to Arguments***

Applicant's arguments filed 09-07-2007 have been fully considered but they are not persuasive.

As pointed out above, the balloon alone of Cohen is not the claimed anchoring module, and therefore, it is irrelevant that it is permanently attached to the guidewire. The guidewire together with the balloon is the claimed anchoring module, and when the balloon is inflated to engage the vessel wall while the balloon guidewire is coupled by the motor to the guide track (inner catheter), the balloon guidewire clearly would act to anchor the guide track in the vessel lumen.

Contrary to applicant's position, Richter's device is certainly not limited to moving a small device within a blood vessel. Clearly Richter contemplates using the disclosed motor drive mechanism to move entire guidewires or catheters along body lumens as noted in the cited passages. Therefore, there would be no reason to surmise that the system would be incapable of moving a

resection catheter into position inside a body lumen. The examiner need not include the endoscope of McAlister in the proposed combination. The fact that McAlister might disclose an endoscope along which the resection catheter is pushed in no way obviates the concept of using a small motor to either move a resection catheter over or inside another tube (catheter or endoscope) or member. It would still act to facilitate the passage of a member through a tortuous body lumen and would protect the lumen wall by pulling the member through as opposed to pushing it through, as taught by Richter. One skilled in the art would have had every reason to expect success when attempting to use a motor drive mechanism to pull a resection catheter such as McAlister's through a body lumen. One skilled in the art would assume that the type of system employed by Richter would be applicable to a myriad of different systems involving the longitudinal positioning or translating of a member through a tube or lumen.

### ***Conclusion***

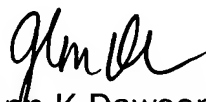
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Glenn K. Dawson whose telephone number is 571-272-4694. The examiner can normally be reached on M-Th 7:30-5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd E. Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Glenn K Dawson  
Primary Examiner  
Art Unit 3731

Gkd  
25 January 2008